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Regeneration Technologies, Inc.



2002 Letter To Shareholders

PROCESSED APR 09 2003



Science · Safety · Innovation

### Forward Looking Statement

This Letter to Shareholders and the documents incorporated by reference contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations, estimates and projections about our industry, our management's beliefs and certain assumptions made by our management. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents the registrant files from time to time with the Securities and Exchange Commission.

## Regeneration Technologies' Mission

Regeneration Technologies' mission is to advance life and revolutionize healing by:

- Expanding the gift of life given by donors and their families
- Pioneering innovations for tissue regeneration
- Dedicating ourselves to excellence, safety and customers
- Demonstrating integrity in everything we do

## **About Regeneration Technologies**

Regeneration Technologies, Inc. is a leader in tissue-based innovations that are used to repair and promote the natural healing of human bone and other human tissues. RTI processes human musculoskeletal and other tissues, including bone, cartilage, tendon, ligament, pericardial and cardiovascular tissue in producing allograft implants. Surgeons then implant these allografts to repair a wide variety of bone and other tissue defects, including spinal vertebrae repair, musculoskeletal reconstruction, fracture repair, periodontal repair, urinary incontinence and heart valve disorders.



#### 2002 Letter to the Shareholders

At the beginning of 2003, Regeneration Technologies Inc. is, in many ways, a different company than we were one year ago. Since our inception, RTI has been a leader in providing safe, biological solutions for surgeons and patients. However, in the past year we have re-evaluated every aspect of our organization, which has led us to enhance the best parts of our company and strengthen others. In the most positive aspects, you will see we have not changed. Our commitment to science, safety and innovation to offer the safest, highest quality allograft implants available is stronger than ever. We have taken what was a very good company and made it even better.

We made significant progress in areas such as donor services, operations, R&D and distribution, which has already led to positive results. The entire RTI organization will continue to work diligently to ensure that the generous gift of tissue donation enhances, or saves, the lives of many. We will continue to build on a formidable foundation, strengthening our reputation as a valuable partner for donor families, recipients, recovery agencies, distribution partners, the medical community, employees and investors. We believe that the enhancements put in place in 2002 will make our continued success possible.

## Rebuild: Management Team

After being named president and chief executive officer of RTI in December 2001, my first task became very clear – to build a team of solid leaders committed to the high standards of quality, safety and leading technology RTI had become known for throughout the industry.

In the past year, we have enhanced our board of directors by adding one position for David J. Simpson, executive vice president of Stryker Corporation. In his 15 years at Stryker, Dave has been key in leading the financial growth of the company. He will be a great asset to the RTI board. Also this past year, one of our long-time directors, Anthony C. Phillips, stepped down from the board. We thank Tony for all he has done for RTI since joining the board of directors in 1998.



Brian K. Hutchison
Chairman, President and Chief Executive Officer

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Roger Rose Vice President of Danor Services



RTI machines allograft into precision-shaped implants using automated equipment.



We built a strong senior management team, which has led to the changes experienced by RTI in the past year. This skilled team has given our employees the focus, drive and direction to make the modifications necessary for our success. Each member of senior management is guided by RTI's vision – through our commitment to science, safety and innovation, we will enhance the gift of tissue donation to create safe, high-quality biological solutions for patients.

Guided by a new leadership vision, every area of our company has seen improvements, which have been crucial to our success in putting RTI back on track this year.

#### Renewal: Donor Services

In the past year, RTI has renewed its commitment to assisting our recovery partners, under the leadership of **Roger Rose**, **vice president of donor services**. Tissue donation is crucial to meeting our goal of helping patients – without the generosity of donor families and the dedicated work of recovery agencies across the country, we could not make life-saving and life-enhancing implants for hundreds of thousands of people. Our tissue recovery network is dedicated to its role as steward of the gift of tissue donation – by educating communities about tissue donation, offering the option of tissue donation to families and honoring the families who have selflessly donated a loved one's tissue.

To strengthen our relationships with our recovery partners and assist them with their initiatives, RTI has increased its focus and resources to our donor services department. We changed the name of our donor services affiliate, U.S. Allograft Network (USAN), to RTI Donor Services, a non-profit corporation dedicated to donated human tissue recovery initiatives. RTI Donor Services works with the numerous recovery agencies, hospitals and funeral homes that provide tissues such as bone, tendons, ligaments, heart valves and cardiovascular tissue to Regeneration Technologies for preparation into biological, allograft implants. Through our donor services initiative, RTI provides tissue recovery agencies with support in the form of donor awareness education and services to donor families.

We have already achieved positive results in tissue donation, including an increase of over 15 percent in musculoskeletal

tissue recoveries in 2002 compared to 2001. In the cardiovascular area, we saw a doubling of recovery relationships in the second half of the year.

Going forward, we look for continued strong relationships with our existing recovery partners, as well as new relationships with additional recovery partners. RTI will focus on bringing the entire industry together to positively affect tissue donation in the United States. Through innovative programs and unparalleled services honoring donor families, the industry can work in unison so that millions of people across the country can walk, stand straight, live pain-free or even extend life through allograft implants.

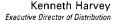
#### Restructure: Distribution

Strong relationships with our distribution and recovery partners will ensure that we reach surgeons and patients with our safe, high quality allograft implants. This year, under the leadership of **Kenneth Harvey**, **executive director of distribution**, RTI restructured our distribution agreements and strategically aligned these partnerships with our fastest growing and most needed product lines. RTI made the strategic decision to move almost entirely away from any direct distribution of our allograft implants, instead concentrating our resources on what we do best – screening, testing and processing of safe, high quality allograft products.

In September 2002, RTI announced new distribution agreements with two major corporate distribution partners: Medtronic Sofamor Danek (MSD) and Exactech Inc. These agreements not only provide more mutually favorable distribution arrangements, but in some cases highlight areas of potential growth through combined R&D efforts.

MSD, the world leader in providing spinal solutions to surgeons and hospitals, will continue to serve as exclusive worldwide distributor for precision machined, specialty allograft tissue and bone paste products processed by RTI for use in spinal surgery. Under the new agreement, RTI and MSD have agreed to co-develop new tissue-based spine surgery solutions and restructure financial terms to reflect the value of RTI's proprietary technology, including its BioCleanse™ Tissue Sterilization Process.







Under the new agreement with Exactech, the company will serve as the exclusive worldwide distributor for bone paste products processed by RTI for non-spinal musculoskeletal orthopedic procedures. RTI and Exactech also have agreed to work together to develop new bone paste products for use in non-spinal musculoskeletal procedures.

In January 2003, we announced a distribution agreement with a new corporate distribution partner, Stryker Endoscopy, Stryker Endoscopy, a leader in the endoscopic field, will serve as the exclusive provider of distribution services in the United States for allograft tissue processed by RTI for use in sports medicine surgeries.

These agreements, with three leading orthopedic and spinal distribution companies, gives RTI a solid base for long-term growth. They free RTI from some of the administrative procedures and expenses related to the distribution of these products, while allowing us access to experienced, focused and well-known distribution forces.

We look forward to solid, long-term relationships with each of our distribution partners. Aligning some of our fastestgrowing product lines - spinal, sports medicine and general orthopedic - with skilled distribution partners focused on customer service and education will increase the use of RTI implants in operating rooms around the world.



Randal Mills, Ph.D. Vice President of Operations and Research and Development

## Revise: Operations and R&D

We made some of our most significant enhancements in the areas of operations and research and development, under the leadership of Randal Mills, Ph.D., vice president of operations and research and development.

In 2002, we moved into our new, state-of-the-art facilities. This includes a 65,000-square-foot, pharmaceutical-grade processing facility that meets or exceeds all existing and proposed industry regulations. The move to this new facility was critical in allowing us to make some very important improvements in the safety and quality of our implants while increasing our efficiency in meeting demand.

Our new facility houses RTI's Next-Generation BioCleanse™ Tissue Sterilization Process. With the use of multiple individual chambers, the Next-Generation BioCleanse process



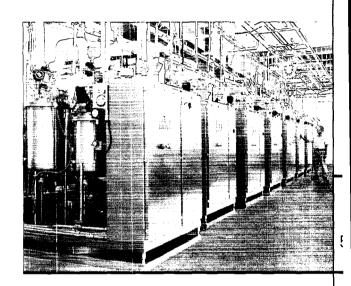
sterilizes tissue from a single donor. BioCleanse – a low-temperature chemical sterilization process – is validated to sterilize tissue, eliminating blood, viruses, fungi and spores while retaining the natural biomechanical and structural properties of the tissue. Current standard methods of sterilization and tissue processing, such as heat, irradiation, ethylene oxide, liquid chemical germicides and aseptic processing, may not provide complete removal of bacteria and viruses and/or have been reported to compromise the biomechanical integrity or biocompatibility of allograft.

Recently, at the American Academy of Orthopaedic Surgeons annual meeting, RTI raised the standard for allograft safety yet again by introducing the implementation of an additional sterilization step for our structural allografts. This will allow us to deliver bone tissue labeled "Sterile," indicating that it meets or exceeds requirements for sterility assurance level (SAL) 10-6 per AAMI and ISO Standards.

Allograft safety has become one the most discussed issues in our industry since the beginning of 2002. RTI made safety of allograft tissue a priority well ahead of the curve, first introducing the BioCleanse Tissue Sterilization Process in March 2000. The BioCleanse process has been clinically proven to be safe – in more than three years in use, RTI has distributed more than 300,000 bone allograft implants across the country with no incidence of recipient infection. Through the BioCleanse process, RTI is redefining tissue sterility by exceeding FDA and current industry standards for sterile tissue processing.

In order to create implants based on actual demand, rather than forecasted demand, RTI transitioned to a demand-focused business model. This model has increased operational efficiency and, importantly, decreased inventory of lesser-used implants. This demand-focused model definitively benefits surgeons and their patients — they will receive necessary implants in a timely manner — while RTI will decrease unused inventory.

In the coming year, RTI will increase our research and development efforts, in conjunction with our corporate distribution partners, to develop new biological solutions to help patients, as well as continue our unending quest to use science, safety and innovation to create the safest, highest-quality allografts in the industry.



At the core of RTI's new state-of-the-art processing facility is the BioCleanse system, featuring fully automated equipment and technology.

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Louis E. Barnes III Vice President of Cardiovascular



Alabama Tissue Center has been a leader in the cryopreservation of cardiovascular allografts for 20 years.



#### Refocus: Alabama Tissue Center - Cardiovascular

In 2002, RTI saw an incredible increase in our cardiovascular allograft distribution, including a five-fold increase in the fourth quarter, compared to the fourth quarter 2001. Our cardiovascular line, processed by our subsidiary, Alabama Tissue Center (ATC), under the leadership of **Louis E. Barnes III, vice president of cardiovascular**, includes cryopreserved valves, conduits, patches, veins and arteries. The increased distribution experienced by ATC can be attributed to obtaining new customers for our cardiovascular products in the past 12 months.

ATC has been a leader in the cryopreservation of cardiovascular allografts for 20 years. Due to our commitment to operational excellence and product leadership, ATC helps patients every day with life-saving and life-enhancing cardiovascular allografts, with no incidence of infection in its 20 years of existence. ATC was re-accredited by the American Association of Tissue Banks in April 2002, reaffirming the program's commitment to voluntary industry oversight, which began with its first accreditation in 1989. The program's 20-year commitment to regulatory compliance and industry oversight has made the safety track record possible.

The increasing demand for our cardiovascular allografts and the long track record of safety and quality of ATC has given us cause to refocus on this area of our business. ATC will begin extensive studies in the coming year evaluating the BioCleanse Tissue Sterilization Process and its application to cardiovascular tissues. We will look at potential expansion of our subsidiary's operations in the coming year to meet the increased need for our cryopreserved cardiovascular grafts.

### Refine: Regulatory Affairs & Quality Assurance

Our regulatory affairs and quality assurance department, under the leadership of Caroline Hartill, vice president of regulatory affairs and quality assurance, is one of the best examples of how we have made enhancements to an already excellent department.

We began the accreditation application process with the American Association of Tissue Banks (AATB) in August 2002. To date, we have filed the application with supporting

documentation and complied with an inspection by AATB officials in February 2003. We look forward to success in our endeavor to become accredited by the AATB and to a long relationship with this important trade organization.

In the third quarter of last year, we submitted our first 510(k) applications to the Food and Drug Administration for our bone paste products. The applications are going through the long review process by the FDA, and we anticipate successful completion in the coming year.

In January 2003, we brought on a **new medical director**, **Lennox Archibald, M.D., MRCP**. Dr. Archibald most recently served as acting medical director of the Epidemic Information Exchange and medical epidemiologist in the National Center for Infectious Diseases at the Centers for Disease Control and Prevention (CDC). His extensive experience in microbiology and epidemiology will insure that RTI meets current protocols for infectious disease screening, as well as advances our screening technologies and methods in anticipation of future industry growth and needs.

We are supportive of the increased scrutiny on tissue banks from the CDC and FDA, and RTI continues to maintain one of the highest safety ratings in the industry for our allograft products. Our proven track record can be attributed in large part to the stringent screening and testing procedures conducted by the RA/QA department. Our screening and testing measures exceed regulatory requirements, as it is our obligation to use every resource available to make the right quality and safety decisions for the benefit of the surgeons who use our implants and their patients.

## Revitalize: Finance

We have built a solid financial structure and foundation for future growth and sustained profitability under the leadership of **Thomas F. Rose, vice president and chief financial officer**.

During the first half of 2002 we reorganized our accounting structure and managed some one-time charges. During the second half of 2002 we continued to revitalize our corporate finances through two key accomplishments. In November, we completed a private placement of 3.8 million shares of common stock, resulting in net proceeds of approximately



Caroline Hartill Vice President of Regulatory Affairs and Quality Assurance



Lennox Archibald, M.D., MRCP









RTI partners with leading orthopedic and spinal companies to distribute allograft implants to surgeons around the world.

\$25.8 million to the company. In December, we signed a \$15.1 million credit agreement with Bank of America. The one-year term loan, which is fully collateralized by cash and investments, repaid RTI's debt under forbearance with Bank of America. These initiatives laid the foundation for positive results in the second half of the year – including record-setting revenues for two consecutive quarters and a return to profitability.

In the coming year, expect financial predictability, integrity and credibility. Financially, RTI will continue to pursue longer-term financing alternatives and achieve sustainable profitability. Our continued implementation of fiscal and operational efficiency programs will drive cost reductions moving forward, and we look to maintain the positive momentum achieved in the second half of 2002.

RTI has been one of the leaders in our industry, focusing on providing surgeons and their patients with the safest, highest quality allograft implants. With the enhancements to our organization made in 2002, strategically improving the best parts of our company, we are now even stronger and poised for long-term success. Our hard work of last year has led to record revenues and solid performance for the second half of 2002. Our goal is to build on that success for the upcoming quarters.

Through solid relationships with the recovery industry, our distribution partners and the medical community, and our commitment to continuously raise the bar for safety, quality and innovation, we intend to improve the tissue industry and drive awareness to the benefits of biological solutions. As we expand on the foundation of success we have built this year, I'd like to thank you for your continued support of Regeneration Technologies.

Brian K. Hutchison

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Chairman, President and Chief Executive Officer

## **Board of Directors**

Brian K. Hutchison Chairman, President & CEO

President, Venad Administrative Services, Inc. Philip R. Chapman General Partner, Adler & Company

Associate Professor & Interim Chairman Peter F. Gearen, M.D. Department of Orthopedics and University of Florida College of Medicine Rehabilitative Medicine

Michael J. Odrich Managing Director Lehman Brothers, Inc.

David J. Simpson Executive Vice President Stryker Corporation

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Audit Committee Philip R. Chapman Peter F. Gearen, M.D. David J. Simpson

Continental Stock Transfer & Trust Transfer Agent New York, New York 10004 2 Broadway 212,509,4000

Corporate Counsel Fulbright & Jaworski L.L.P. 666 Fifth Avenue New York, New York 10103 31st Floor 212.318.3000

Annual Shareholder's Meeting University of Florida Hotel & Conference Center Monday, April 28, 2003, 10:00 a.m. 1714 SW 34th St., Gainesville, FL 32607

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